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10/593,608	09/21/2006	Yoichi Kato	188-105	2576
28349 7590 12/30/2009 DILWORTH & BARRESE, LLP 1000 WOODBURY ROAD SUITE 405 WOODBURY, NY 11797				
EXAMINER				
NAFF, DAVID M.				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/593,608

**Applicant(s)**

KATO ET AL.

**Examiner**

David M. Naff

**Art Unit**

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 October 2009.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.  
4a) Of the above claim(s) 6 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-5 and 7-16 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/22)  
4) ☐ Interview Summary (PTO-413)  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_  
Paper No(s)/Mail Date \_\_\_\_\_

### DETAILED ACTION

An amendment of 10/2/09 amended claim 1, and added new claims 14-16.

Claims in the application are 1-16.

Claim 6 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being  
5 drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/9/09.

Claims examined on the merits are 1-5 and 7-16.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

10 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15 Claims 1-5 and 7-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20 The specification fails to recite or support "A porous body comprising, a porous sericin skeleton constituent" in lines 1 and 2 of claim 1. The specification discloses a porous body comprising sericin as skeleton constituent, or a porous body having a skeleton made entirely of sericin. If the skeleton is formed entirely of sericin, the sericin skeleton is the porous body, and the porous body does not comprise a porous sericin skeleton constituent. Disclosure is not  
25 found of a porous sericin skeleton being a "constituent". If claim 1 intends to require a skeleton made entirely of sericin, it is suggested the portion of claim 1 from "A" in line 1 to "constituent" in line 2, be replaced with --- A porous body consisting of a porous skeleton formed

of a material consisting of sericin ---. With this change, dependent claim 4 should be amended by replacing "containing" in line 1 with --- consisting of ---, and cancel "in an". In line 2 of the claim, replace "state" with --- in the skeleton ---. This type of change should also be made to dependent claims 8-10.

5           The specification fails to recite or support "A porous body comprising a skeleton consisting essentially of sericin" as required in line 1 of claim 13. Disclosure is not found of a skeleton "consisting essentially" of sericin. There is support for only a skeleton consisting of sericin. Additionally, support is not found of a porous body comprising a skeleton. When a skeleton is present, the skeleton is the porous body, and the porous body consists of the  
10   skeleton.

Support is found in the specification for a porous body prepared as required by claim 15, which does not have a recovery rate of 10% to 100% after 50% compression as required in claims 1 and 14.

***Claim Rejections - 35 USC § 112***

15           The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

          Claims 1-5, 7-14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being  
20   indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

          Claim 1 and claims dependent on claim 1 are unclear by "'porous body comprising, a porous sericin skeleton constituent" being unclear as to meaning and scope. Structure resulting from a porous body comprising a porous sericin skeleton constituent is uncertain since the  
25   specification fails to describe a porous body comprising a porous sericin skeleton constituent.

Claims 4, 5 and 8-13 are unclear where in the porous body the functional substance is immobilized, i.e., in or outside the porous sericin skeleton constituent.

Claim 14 is unclear by "consisting essentially of" being uncertain as to meaning and scope. The specification does not recite this limitation, materials permitted and excluded by the  
5 limitation is uncertain.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

10 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later  
20 invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyakarnam et al (6,365,149) in view of Tsubouchi (7,115,388) (newly applied).

25 The claims are drawn to a porous body, comprising, as a porous sericin skeleton constituent, where the sericin has an average molecular weight of 30000 to 400000, and having a recovery rate of 10% to 100% after 50% compression. Also claimed is a porous body comprising a skeleton consisting essentially of sericin with an average molecular weight of 30,000 to 40,000, and having a recovery rate of 10% to 100% after 50% compression.

Vyakarnam et al disclose porous foam scaffoldings for repair or regeneration of tissue. The foam scaffolding may be seeded with cells, and implanted (col 32, lines 1-4 and 30-32). The foam has pores of 30-200  $\mu\text{m}$  in size (col 5, lines 1-3), and porosities ranging from about 20% to about 98% (col 4, line 32). Various proteins and therapeutic agents can be added to the foams during processing, adsorbed onto the surface, or back filled into the foams after the foams are made (col 17, lines 39-67). Bioactive coatings or surface treatments can be attached to the surface of the foams. Bioactive peptide sequences can be attached to facilitate protein adsorption and subsequent cell attachment (col 17, lines 62-65). The foam may be prepared using a procedure that involves gelation (col 12, line 38) or solidifying a polymer solution (col 14, lines 21-30).

Tsubouchi discloses that a sericin solution gels if there is no shear (col 2, lines 58-60). Also disclosed (col 4, lines 16-27 and 14, line 57 to col 15, line 40), is obtaining polypeptides from fibroin or sericin, and gelling the polypeptides to form materials for various uses due to advantageous properties (col 4, lines 19-22) of cell-growth promoting activity and excellent touch and extensibility. The polypeptides can have a molecular weight of 40,000 to 150,000 (col 8, line 26).

When producing a foam scaffolding by gelatin as disclosed by Vyakarnam et al, it would have been obvious to use sericin or a polypeptide therefrom to form the gel as suggested by Tsubouchi disclosing gel formation with sericin or polypeptide from sericin to obtain benefits of sericin or the polypeptide having excellent cell growth-promoting activity and excellent touch and extensibility. The excellent cell growth-promoting activity of sericin or the polypeptide would have been motivation to use sericin or the polypeptide to form a gel as the scaffolding of Vyakarnam et al since the scaffolding of Vyakarnam et al can contain cells, which promoting the growth of would have been desirable. The claims encompass a polypeptide from sericin as

disclosed by Tsubouchi since the claims encompass a molecular weight for sericin as low as 30,000. A molecular weight of 30,000 will be a polypeptide from sericin rather than sericin since sericin has a molecular weight of 400,000. A gel resulting from gelling sericin or the polypeptide therefrom will inherently have a recovery after compression as required by claim 1. The  
5 conditions of dependent claims would have been obvious from the conditions disclosed by the references.

### ***Response to Arguments***

The amendment urges that there is no suggestion to substitute the skeletal matrix of Vyakarnam et al with sericin. However, Tsubouchi discloses that sericin and a polypeptide  
10 therefrom forms a gel having cell growth-promoting activity. Since the scaffold of Vyakarnam et al may be formed by gelation, it would have been obvious to use sericin or polypeptide therefrom to form the scaffold of Vyakarnam et al as a sericin or polypeptide gel to obtain the cell growth-promoting activity of sericin or the polypeptide since the scaffold of Vyakarnam et al may contain cells. This rejection is not based on filling voids of the scaffold of Vyakarnam et al  
15 with sericin or the polypeptide, but on forming the scaffold using sericin or the polypeptide.

### ***Conclusion***

Claims 15 and 16 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner  
20 can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/  
Primary Examiner, Art Unit 1657

DMN  
12/26/09